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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,206

09/14/2006

Irina Velikyan

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,206	Applicant(s) VELIKYAN ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 8-12 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,3-7,11,13,15 of copending Application No. 10/552,134 as stated in the office action mailed 9/5/07. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The rejection is maintained as the claims have not been amended and the copending application 10/552,134 has not been abandoned.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 1618

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1,2,6-14 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-14 of

copending Application No. 11/358,681 as stated in the office action mailed 9/5/07. This

is a provisional obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented. The rejection is maintained as a terminal

disclaimer has not been filed.

5. Claims 1-14 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-15 of

copending Application No. 10/552,134 as stated in the office action mailed 9/5/07. This

is a provisional obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented. The rejection is maintained as a terminal

disclaimer has not been filed.

Response to Arguments

6. Applicant's arguments filed 2/5/08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397A2) in view of Bottcher et al. (US 5,439,863) and further in view of Maier-Borst et al. (GB 2056471A) as stated in the office action mailed 9/5/07.

9. Applicant asserts that Bottcher et al. does not use the microwave activation technique disclosed in the present invention to carry out the coordination chemistry but merely mentions in passing that the input energy can also take place through the effect of ultrasound, microwave or a laser beam. Applicant asserts that Bottcher et al. does not elaborate or even further discuss any of these possible inputs of energy.

10. Bottcher et al. does teach that the formation of the complexes themselves will be accelerated through high energy input or through the effect of microwaves (column 3, lines 38-45). The reference of Bottcher et al. is a patent and therefore contains an enabling disclosure. The limitation of using microwaves to form the complexes does not need to be exemplified.

11. Applicant asserts that it is clear that Bottcher et al. does not deem these inputs of energy as important parts of its patent.

12. The limitation of using microwaves to form the complexes does not need to be exemplified and the assertion is merely the opinion of the applicant.

13. Applicant asserts that Bottcher et al. presents using three separate inputs of energy on merely two lines throughout the entire patent.

14. Bottcher et al. does teach that the formation of the complexes themselves will be accelerated through high energy input or through the effect of microwaves in column 3, lines 38-45 and column 5, line 66. The limitation of using microwaves to form the complexes does not need to be exemplified.

15. Applicant asserts that if Bottcher et al. used the same microwave technology, such as a microwave oven, utilized in the present invention then Bottcher et al. would have found that the use of microwave activation substantially improves the efficiency and reproducibility of its neutral metal complex salt formation.

16. Bottcher et al. does teach that the formation of the complexes themselves will be accelerated (improved efficiency) through high energy input or through the effect of microwaves (column 3, lines 38-45). The limitation of using microwaves to form the complexes does not need to be exemplified.

17. Applicant asserts that in the present invention, gallium-68 is elute from a commercial generator in ionic form, that it is important to purify the $^{68}\text{Ge}/^{68}\text{Ga}$ eluate from competing metal ions and that the ability of metal ions to form complexes of metals differs. Applicant also asserts that the instant claims consider the preconcentration of

Art Unit: 1618

gallium-68 which is needed for the efficiency of the labeling complexing reaction and that taking into account that the preconcentration procedure is based on the gallium ion ability to form GaCl_4^- complex, gallium can be purified from the competing metal ions using the anion-exchange column.

18. Applicant asserts that the reference of Maier-Borst et al. is aimed to synthesize an anion exchange resin for the separation of gallium-68 from germanium-68 thus avoiding the use of EDTA for elution as it was done before the 1980's.

19. The instant claims are drawn to the method of obtaining ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ generator with an anion exchanger, such as polystyrene-divinylbenzene and a dilute HCl solution. The method of Maier-Borst et al. is drawn to obtaining ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ generator with an anion exchanger, such as styrene and divinylbenzene and a dilute HCl solution (p1, lines 59-63) and therefore the method of Maier-Borst et al. encompasses the method of the instant claims. The instant claims do not provide the limitations of a preconcentration procedure.

Conclusion

No claims allowed at this time.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1618

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618